because § 924(c)(1)(A)(iii) does not increase the maximum statutory penalty for "using and carrying" a firearm in relation to a crime of violence, we conclude that the sentence imposed on Pounds by the district court is correct.

AFFIRMED.

PURDUE PHARMA L.P. and The Purdue Frederick Company, Plaintiffs–Appellants,

v.

FAULDING INC., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co., Defendants–Cross–Appellants,

and

Zeneca Inc., Defendant.

Nos. 99–1416, 99–1433.

United States Court of Appeals, Federal Circuit.

DECIDED: Oct. 25, 2000

Owner of patent claiming methods of treating pain in patients by administering a sustained-release opioid once a day brought infringement action against competitor. After bench trial, the United States District Court for the District of Delaware, Joseph J. Farnan, Jr., J., 48 F.Supp.2d 420, found that competitor had infringed patent but that claims at issue were invalid. Owner appealed, and competitor cross-appealed. The Court of Appeals, Bryson, Circuit Judge, held that: (1) limitation which provided that maximum plasma concentration was to be more than twice the plasma level of the opioid at about 24 hours after its administration was not supported by the disclosure as originally filed; (2) district court properly evaluated written description issue; and (3) district court was not required to defer to findings of patent examiner.

Affirmed.

1. Patents ⇐99

In order to satisfy the patent statute's written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue; nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. 35 U.S.C.A. § 112.

2. Patents ⇐99

In order to satisfy the patent statute's written description requirement, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims; inquiry is a factual one and must be assessed on a case-by-case basis. 35 U.S.C.A. § 112.

3. Patents ⇐324.55(3.1)

When the question whether a patent satisfies the written description requirement is resolved by a district court sitting as the trier of fact, Court of Appeals reviews the court's decision for clear error. 35 U.S.C.A. § 112.

4. Patents ⇐99

Limitation in patent for method of treating patients with sustained-release opioid, which provided that maximum plasma concentration was to be more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, was not supported by specification's description of invention as having a generally flat or substantially flat morphine plasma concentration curve, for purpose of written description requirement, absent evidence that person skilled in the art would interpret term "flat" to be limited to a concentration level ratio less than or equal to two. 35 U.S.C.A. § 112.

5. Patents ⇐99

Limitation in patent for method of treating patients with sustained-release opioid, which provided that maximum plasma concentration was to be more than twice the plasma level of said opioid at about 24 hours after administration of the

dosage form, was not supported by examples in patent in which morphine formulation had claimed ratio, for purpose of written description requirement, where other examples in patent did not have claimed ratio, and there was nothing in patent that would direct skilled artisan to ratio as an important aspect of the invention. 35 U.S.C.A. § 112.

6. Patents ⇐99

Patentee's assertion that it claimed narrower range, in patent for method of treating patients with sustained-release opioid, for ratio of maximum plasma concentration to plasma level of opioid at 24 hours after its administration than was disclosed in examples in patent specification was immaterial to whether claims met written description requirement, where specification did not clearly disclose to skilled artisan that ratio was part of invention. 35 U.S.C.A. § 112.

7. Patents ⇐99

District court's statement, in finding that patent for method of treating patients with sustained-release opioid did not meet written description requirement, that court viewed examples collectively because there was no way to determine which examples embodied invention, did not establish that court improperly required patentee to identify what was invention and what was not; court was merely noting that it had to view examples collectively because specification did not state that any particular examples pertained to invention recited in amended claims.

8. Patents ⇐99

To find that amended patent claims meet written description requirement, support for the invention as defined by those claims must be found in the specification as filed, and the amended claims may not be used to provide that support. 35 U.S.C.A. § 112.

9. Patents ⇐112.3(1)

District court was not required to defer to finding of patent examiner that new claims added to patent application were "supported by the specs," in determining whether claims met written description requirement, as court found that examiner's statement was not persuasive in light of all the evidence in the case. 35 U.S.C.A. § 112.

10. Patents ⇐112.3(1)

Despite deference given to decision of Patent and Trademark Office (PTO) with respect to patentability in district court litigation, in form of presumption of validity that is accorded to issued patents, court was not bound by examiner's finding in ex parte application proceeding that patentee's amended claims were supported by the specification, particularly where court heard extensive evidence on the issue in an adversary hearing, none of which was before the patent examiner. 35 U.S.C.A. § 282.

S. Leslie Misrock and Victor N. Balancia, Pennie & Edmonds LLP, of New York, New York, argued for plaintiffs-appellants. With them on the brief was Todd A. Wagner, and Stanton T. Lawrence, III, Pennie & Edmonds LLP, of Washington, DC.

Steven J. Lee, Kenyon & Kenyon, of New York, New York, argued for defendants-cross appellants. With him on the brief were Paul H. Heller, Edward J. Handler, III, Charles A. Weiss, William G. James, II, and Mark I. Koffsky. Of counsel on the brief was E. Brendan Magrab, Faulding Inc., of Elizabeth, New Jersey. Of counsel were Jack B. Blumenfeld, and Karen Jacobs Louden, Morris, Nichols, Arsht & Tunnell, of Wilmington, Delaware.

Before PLAGER, Circuit Judge, SMITH, Senior Circuit Judge, and BRYSON, Circuit Judge.

BRYSON, Circuit Judge.

Purdue Pharma L.P. and The Purdue Frederick Company (collectively Purdue) own U.S. Patent No. 5,672,360 (the '360 patent), which is drawn to methods of treating pain in patients by administering

an opioid, such as morphine, once a day. Purdue brought a patent infringement suit against Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co. (collectively Faulding) in the United States District Court for the District of Delaware. After a bench trial, the district court found that Faulding had infringed the asserted claims of the '360 patent but that the claims were invalid. Purdue appeals from the finding of invalidity, and Faulding cross-appeals from the finding of infringement. We uphold the court's ruling invalidating the asserted claims of the '360 patent; we do not reach Faulding's cross-appeal on the issue of infringement.

I

In 1984 Purdue introduced a sustained-release, twice-a-day oral morphine formulation. Sustained-release formulations represent a significant advance over immediate-release morphine formulations because immediate-release formulations need to be administered every four hours, a schedule that interferes with the patient's sleep and subjects the patient to cycles of pain that are difficult to control.

After its success with its twice-a-day formulation, Purdue sought to develop a sustained-release oral morphine formulation that would need to be administered only once a day. The work of its researchers initially led to the issuance of U.S. Patent No. 5,478,577 (the '577 patent), which discloses a once-a-day formulation exhibiting a rapid initial rise in the opioid concentration in the patient's blood.

During the same period, Faulding was developing long-lasting opioid anti-pain formulations as well. In 1996, Faulding began marketing its oral sustained-release morphine formulation in the United States under the trade name Kadian. The package insert accompanying Kadian states that it may be administered either once or twice a day.

Shortly after Faulding began selling Kadian in this country, Purdue brought suit against Faulding and Zeneca Inc., alleging that the manufacture, sale, and use of Kadian as a once-a-day morphine formulation infringed the '577 patent. At the time the suit was filed, the inventors of the '577 patent had pending before the Patent and Trademark Office U.S. Patent Application Serial No. 08/578,688 (the '688 application), which claimed priority to the application that led to the '577 patent.

While the litigation over the '577 patent was pending, Purdue's counsel canceled the pending claims of the '688 application and amended the application to add all new claims. The application was allowed as amended, and it issued as the '360 patent on September 30, 1997. No art rejections were made against the issued claims. The only prosecution history is contained in a handwritten interview summary in which the examiner stated that the new claims are supported by the specs.

Purdue asserts that the once-a-day formulation described in the treatment method of the '360 patent, which results in a substantial fluctuation in the opioid concentration in the patient's blood between the maximum concentration level and the concentration level at the end of the 24-hour dosage period, was contrary to the prevailing view at the time that sustained-release formulations should produce minimal fluctuations in the opioid concentration level during the dosing interval. That aspect of the invention is reflected in each of the claims of the '360 patent, including claims 2, 4, and 11, the three asserted claims at issue in this case. Claims 1 and 9, on which the three asserted claims depend, both contain a limitation requiring that the maximum plasma concentration of the opioid be more than twice the plasma level of the opioid 24 hours after administration of the drug. The pertinent claims of the '360 patent at issue in this case read as follows:

1. A method of effectively treating pain in humans, comprising orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an

opioid analgesic or salt thereof which upon administration provides a time to maximum plasma concentration (T_{max}) of said opioid in about 2 to about 10 hours and a maximum plasma concentration (C_{max}) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, and which dosage form provides effective treatment of pain for about 24 hours or more after administration to the patient.

2. The method of claim 1, wherein the T_{max} occurs in about 2 to about 8 hours after oral administration of said dosage form.

4. The method of claim 1, wherein said opioid analgesic is morphine sulfate.

9. A method of effectively treating pain in humans, comprising orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an opioid analgesic or salt thereof which at steady-state provides a time to maximum plasma concentration (T_{max}) of said opioid in about 2 to about 10 hours and a maximum plasma concentration (C_{max}) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, and which dosage form provides effective treatment of pain for about 24 hours or more after administration to the patient.

11. The method of claim 9, wherein said opioid analgesic is morphine sulfate.

Shortly after the '360 patent issued, Purdue amended the complaint in the pending litigation against Faulding and Zeneca by dropping its claims under the '577 patent and asserting infringement of the '360 patent. Faulding and Zeneca asserted various counterclaims, including non-infringement and invalidity, and a bench trial was held on liability. During trial, the district court dismissed the claims against Zeneca. Following the trial, the court held that Faulding's production and sale of Kadian infringed the asserted claims of the '360 patent, but that the claims were invalid because they lacked the written description required by 35 U.S.C. § 112, first paragraph. The court then entered final judgment on the tried issues under Fed.R.Civ.P. 54(b).

II

The validity issue in this case is whether the limitation a maximum plasma concentration (C_{max}) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form [C_{24}] was adequately described in the disclosure of the '688 application as originally filed. The trial court found that it was not.

[1–3] In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue. *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. *Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64, 19 USPQ2d 1111, 1117 (Fed.Cir.1991). Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. *Waldemar Link GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558, 31 UPSQ2d 1855, 1857 (Fed.Cir.1994). That inquiry is a factual one and must be assessed on a case-by-case basis. *See Vas–Cath*, 935 F.2d at 1561, 19 USPQ2d at 1116 (Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis.). When the question whether a patent satisfies the written description requirement is resolved by a district court sitting as the trier of fact, we review the court's decision for clear error. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158, 47 USPQ2d 1829, 1832 (Fed.Cir.1998); *Gen-*

try Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1502 (Fed.Cir.1998).

Purdue contends that the district court made various legal errors in its analysis of the written description issue and that its factual finding on that issue was clearly erroneous. Turning first to the district court's factual analysis, we conclude that the court's finding on the written description issue did not constitute clear error.

A

The district court found that the specification of the '360 patent fails to convey that the C_{max}/C_{24} limitation was encompassed within Purdue's original invention. Purdue attacks that finding on several fronts, but its arguments are unpersuasive.

1

[4] Purdue first argues that the C_{max}/C_{24} limitation is supported by the portion of the specification that describes the invention as not having a generally flat or substantially flat morphine plasma concentration curve. The passage of the specification on which Purdue relies reads as follows:

> The state-of-the-art approach to controlled release opioid therapy is to provide formulations which exhibit zero order pharmacokinetics and have minimal peak to trough fluctuation in opioid levels with repeated dosing. This zero order release provides very slow opioid absorption, and a generally flat serum concentration curve over time. A flat serum concentration curve is generally considered to be advantageous because it would in effect mimic a steady-state level where efficacy is provided but side effects common to opioid analgesics are minimized....
>
> It has now been surprisingly discovered that quicker and greater analgesic efficacy is achieved by 24 hour oral opioid formulations which do not exhibit a substantially flat serum Concentration curve, but which instead provide a more rapid initial opioid release so that the minimum effective analgesic concentration can be more quickly approached in many patients who have measurable if not significant pain at the time of dosing.... Also surprising and unexpected is the fact that while the methods of the present invention achieve quicker and greater analgesic efficacy, there is not a significantly greater incidence in side effects which would normally be expected as higher peak plasma concentrations occur.

'360 patent, col. 5, ll. 24–55. The district court disagreed with Purdue's argument that the phrase formulations which do not exhibit a substantially flat serum Concentration curve refers to the C_{max}/C_{24} ratio of more than two that was added in the amended claims. Instead, the court concluded that the term refers to the feature of rapid opioid release that was recited in the original claims of the application and was described in the specification as critical to the invention. The court's finding is supported by the context in which the statement appears, and it is consistent with the claims as originally filed, which defined the formulation as providing an initially rapid rise ... by providing an absorption half-life [*i.e.*, the time required for one-half of the absorbable opioid to be absorbed into the plasma] from about 1 to 8 hours.

In addition to finding that the substantially flat language in the specification did not refer to the C_{max}/C_{24} limitation, the trial court found that even if that language were understood to relate to the fluctuation in opioid concentration in the blood between the maximum concentration level and the concentration level after 24 hours, one skilled in the art would not understand the term substantially flat to mean a fluctuation of 100% or less.

At trial, Purdue offered expert testimony that the term flat is understood in the field to mean a fluctuation of 100% or less in the concentration of opioid between the maximum level and the level after 24 hours, *i.e.*, a C_{max}/C_{24} ratio of two or less.

The court, however, was unpersuaded. As the court explained, one of Purdue's experts, Dr. Goldenheim, described another sustained-release morphine formulation, Roxanol SR, as having a flat serum concentration curve, even though he acknowledged that it has a fluctuation of over 100%. In addition, the court found that the publications relied upon by Purdue did not substantiate Purdue's assertion that flat means fluctuations of 100% or less. Moreover, the court stated that even if it accepted Purdue's argument that flat means a fluctuation of 100% or less, the use of the modifier "substantially" in the specification, indicates that the word "flat" as used in the '360 patent specification, does not even refer to the precise quantification urged by Purdue.

One of the publications Purdue relied on at trial was International Publication Number WO 94/22431, on which Kabi Pharmacia AB was the applicant. The Kabi application provides pharmacokinetic profiles for two different morphine formulations, CR–A and CR–B. The trial court found that for the CR–A formulation the C_{max} level was more than twice as great as the C_{24} level, and that for the CR–B formulation the C_{max} level was less than twice as great as the C_{24} level. Nonetheless, the Kabi application described both formulations as having low fluctuations. The court therefore found that the Kabi application fails to support Purdue's contention that one skilled in the art understands "flat" to mean fluctuations of less than 100%.

Purdue argues that Kabi's CR–A is a twice-a-day formulation and that the court's reliance on that formulation was therefore misplaced. As noted by Faulding, however, the data in the Kabi application was based on the administration of a single dose of morphine. For that reason, the court was not mistaken in relying on the description of the C_{max}/C_{24} ratio for the CR–A formulation in concluding that the Kabi application fails to support Purdue's argument that one skilled in the art would interpret substantially flat to mean a C_{max}/C_{24} ratio of two or less.

Purdue also argues that the trial court was confused with respect to Dr. Goldenheim's testimony regarding Roxanol SR, which Dr. Goldenheim characterized as having a flat profile. Purdue argues that Roxanol SR is approved only as an eight-hour formulation and that the C_{max}/C_8 ratio of Roxanol SR is less than 2. On cross-examination, however, Dr. Goldenheim was asked to calculate a C_{max}/C_{12} ratio for Roxanol SR from an article containing pharmacokinetic studies of the drug. From the data presented in the paper, Dr. Goldenheim determined that the C_{max}/C_{12} ratio for Roxanol SR is greater than two, and he characterized that C_{max}/C_{12} ratio as pretty flat.

That evidence is meaningless, Purdue asserts, because Roxanol is not described as being approved for twice-a-day administration. Dr. Goldenheim's testimony on cross-examination, however, related to the morphine concentration in the Roxanol SR formulation after 12 hours, and the district court reasonably interpreted Dr. Goldenheim's testimony as a concession that a C_{max}/C_{12} ratio greater than two would still be considered flat. From that evidence, the district court permissibly concluded that a person skilled in the art would not necessarily interpret the term flat to be limited to a concentration level ratio less than or equal to two.

Finally, Purdue asserts that the trial court erroneously failed to consider the teachings of the Morella patents. Those patents, Purdue contends, establish that by 1993 it was understood in the field that a flat pharmacokinetic profile constituted a profile having fluctuations of 100% or less. For example, Purdue argues, U.S. Patent No. 5,202,128, to Morella et al. states that an advantage of the morphine formulations of the invention is that the peak-to-trough variation will be between 60% and 100%, which has been described as a flat plasma morphine concentration time profile. Purdue, however, does not point to anything in the Morella patents that suggests that if the peak-to-trough variation is greater

than 100%, the concentration profile would not be considered flat. The Morella patents therefore do not in any way undermine the district court's finding that a person of ordinary skill in the art would not understand the term substantially flat to denote a C_{max}/C_{24} ratio of two or less.

2

[5] Purdue argues that even if the passage from the specification referring to the substantially flat serum Concentration curve does not provide the required written description for the C_{max}/C_{24} ratio recited in the claims, the examples set forth in the patent provide adequate support for that limitation. Purdue relies on Example 1 (fed and fasted) and Example 3 (fed only) to support the claimed limitation, as the morphine formulation in both examples resulted in a C_{max}/C_{24} ratio greater than two.

The district court rejected Purdue's argument, pointing out that the specification also contains examples in which the C_{max}/C_{24} ratio is less than two and that nothing in the specification indicates to the skilled artisan which examples embody the claimed invention and which do not. We conclude that the district court did not commit clear error in finding that the examples do not provide sufficient support for the C_{max}/C_{24} limitation.

The specification sets forth seven examples. Values for C_{max} and C_{24} are provided for only the first three. Other pharmacokinetic data are provided as well, and morphine concentrations are provided for times other than 24 hours after administration of the drug. Although the examples provide the data from which one can piece together the C_{max}/C_{24} limitation, neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes the C_{max}/C_{24} ratio. The district court therefore reasonably concluded that one of ordinary skill in the art would not be directed to the C_{max}/C_{24} ratio as an aspect of the invention.

The case of *In re Ruschig*, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ 118 (1967), is instructive here. In that case our predecessor court affirmed the holding of the Patent Office Board of Appeals that one of the claims, adopted for purposes of interference, was not supported by the disclosure. The claim at issue in that case was directed to a single compound. The applicants argued that, although the compound itself was not disclosed, one skilled in the art would find support for the claimed compound in the general disclosure of the genus of compounds to which the claimed compound belonged. The *Ruschig* court rejected that argument, stating that

> [i]t is an old custom in the woods to mark trails by making blaze marks on the trees. It is of no help in finding a trail or in finding one's way through the woods where the trails have disappeared—or have not yet been made, which is more like the case here—to be confronted simply by a large number of unmarked trees. We are looking for blaze marks which single out particular trees. We see none.

Id. at 994–95, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ at 122. Although this case differs from *Ruschig* in that what was disclosed in *Ruschig* was a genus encompassing potentially half a million compounds, the rationale applies equally to this case, in which the disclosure of the '360 patent discloses a multitude of pharmacokinetic parameters, with no blaze marks directing the skilled artisan to the C_{max}/C_{24} ratio or what value that ratio should exceed. *See id.* at 994, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ at 122 (Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that naming is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required.). As *Ruschig* makes clear, one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree

must be in the originally filed disclosure. *See id.* at 994–95, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ at 122; *Fujikawa*, 93 F.3d at 1570–71, 39 USPQ2d at 1905; *Martin v. Mayer*, 823 F.2d 500, 505, 3 USPQ2d 1333, 1337 (Fed.Cir.1987) (It is "not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure.... Rather, it is a question whether the application necessarily discloses that particular device.") (quoting *Jepson v. Coleman*, 50 C.C.P.A. 1051, 314 F.2d 533, 536, 136 USPQ 647, 649–50 (1963)). Under that standard, we conclude that the district court did not commit clear error in finding that nothing in the '688 application "necessarily" ... described the later claimed subject matter of the '360 patent. *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790 (Fed.Cir. 1998).

In the case of the '360 patent, there is nothing in the written description of Examples 1 and 3 that would suggest to one skilled in the art that the C_{max}/C_{24} ratio is an important defining quality of the formulation, nor does the disclosure even motivate one to calculate the ratio. For example, the description of Example 1 states that

> [p]lasma morphine concentrations were used for calculation of phamacokinetic parameters including: (a) absorption and elimination rates; (b) area under the curve (AUC); (c) maximum plasma concentration (C_{max}); (d) time to maximum plasma concentration [([T_{max}); (e) $T_{1/2}$ (elimination).

'360 patent, col. 16, ll. 24–29. Figure 9 of the patent graphically represents the mean morphine plasma concentration-time profile for Examples 1 and 2, as well as for the control formulation, MS–Contin. In discussing Figure 9, the disclosure merely states that it can be seen that the formulation of Example 1 attains a higher and earlier C_{max} but a slightly lower extent of morphine absorption than the formulation of Example 2. *Id.* at col. 21, ll. 8–11.

These statements and the calculation of the listed pharmacokinetic parameters are consistent with how the inventors characterize the invention, as the specification states earlier that inventive sustained release once-a-day formulations may be characterized by the fact that they are designed to provide an initially rapid rate of rise in the plasma concentration of said opioid characterized by providing an absorption half-life from about 1 to about 8 hours, '360 patent, col. 6, ll. 1–5, and also that the inventive formulations may be further characterized by having a surprisingly fast time to peak drug concentration (*i.e.*, t_{max}), *id.* at col. 6, ll. 10–12. As can be seen from these excerpts from the specification, however, there is nothing in the written disclosure as originally filed directing the skilled artisan to the C_{max}/C_{24} ratio.

What the '360 patentees have done is to pick a characteristic possessed by two of their formulations, a characteristic that is not discussed even in passing in the disclosure, and then make it the basis of claims that cover not just those two formulations, but any formulation that has that characteristic. This is exactly the type of overreaching the written description requirement was designed to guard against. *See Vas–Cath*, 935 F.2d at 1561, 19 USPQ2d at 1115 (Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.) (quoting *Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 551, 211 USPQ 303, 321 (3d Cir.1981)).

3

[6] Purdue characterizes this case as one in which, at bottom, the applicants claimed less than they disclosed. Using the data from Examples 1 and 3, the skilled artisan can establish a range for the C_{max}/C_{24} ratio of 1.28 to 3.43. Thus, according to Purdue, the claim limitation requiring C_{max}/C_{24} to be greater than two is narrower than the range disclosed in the specification. Purdue asserts that it did

not consider claims in which the C_{max}/C_{24} ratio was less than two to be patentable in light of the prior art, and that its willingness to settle for claims narrower than the invention it disclosed does not create a written description problem.

Because the specification does not clearly disclose to the skilled artisan that the inventors of the '360 patent considered the C_{max}/C_{24} ratio to be part of their invention, it is immaterial what range for the C_{max}/C_{24} ratio can be gleaned from the examples when read in light of the claims. There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the claims carved out a patentable portion.

B

Apart from the asserted factual flaws in the district court's analysis, Purdue contends that the trial court committed several errors of law that affected the court's analysis of the written description issue and require reversal. We have examined each of the claimed legal errors and conclude that the district court did not commit any error of law that had a material effect on the court's judgment.

1

[7] First, Purdue argues that the district court applied the wrong legal test for determining whether the written description requirement was satisfied. Purdue acknowledges that the district court recited the correct test, as set forth in this court's decision in the *Vas–Cath* case, *supra*, but argues that the court actually applied a different test—one that was specifically rejected in *Vas–Cath*. In particular, Purdue relies on a statement in the district court's opinion in which the court commented that viewing the examples collectively, as the Court believes must be done because there is no way to determine which embody the invention and which do not, the examples illustrate a range between 1.48 and 3.43. That comment, according to Purdue, shows that the district court required the specification to set forth what the invention is and what it is not, which is not the correct test under the written description requirement.

Purdue has misinterpreted the quoted passage from the district court's opinion. The court did not insist that the examples identify exactly what constitutes the claimed invention and what does not; instead, the court simply noted that it had to view all of the examples collectively because the specification did not state that any particular examples pertained to the invention that was recited in the amended claims. Under the circumstances, it was entirely appropriate for the district court to view all of the examples together in its effort to determine whether the disclosure as filed contained a sufficient written description of the invention; indeed, that approach was necessary in order for the court to determine that the inventor had possession at that time of the later claimed subject matter. *Vas–Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116.

Purdue makes the related contention that the district court did not view the disclosure as a whole in determining whether the written description requirement was satisfied. Again, we read the district court's opinion differently. Although the district court discussed the examples and the text of the specification separately, it is clear from the court's opinion that it concluded that the specification as a whole did not support the asserted claims of the '360 patent; there is nothing in the court's opinion suggesting that the court considered that any one segment of the specification, standing alone, had to provide the full support for the amended claims.

2

[8] Purdue next argues that the district court committed legal error by looking to the written description portion of the patent, rather than the claims, to define the invention for purposes of the written description analysis. The district court made no error in this regard. The

court noted that it must necessarily look to the claim language to determine if the specification supports what is now claimed, and it further explained that it could not consider the amended claims themselves, which did not appear in the application as filed, to show that at the time of filing the inventor was in possession of what is now claimed. We interpret those remarks as simply articulating the correct legal principles that the amended claims define the invention, that the support for the invention must be found in the specification as filed, and that the amended claims could not be used to provide that support.

3

[9] Finally, Purdue contends that the district court improperly disregarded the findings of the examiner, who stated in an interview summary at the time the amended claims were added to the application that the new claims are supported by the specs. Purdue argues that the district court should have deferred to the examiner's finding on that issue and that the district court failed to do so because the court improperly regarded the written description issue to be an issue of law rather than an issue of fact.

It is true that the district court at one point in its opinion characterized validity as an issue of law. Notwithstanding that isolated statement, the court's lengthy and thorough opinion makes it abundantly clear that the court understood that the question whether the written description requirement was satisfied is a question of fact. Moreover, the district court expressly addressed the examiner's statement on which Purdue relies and found it insufficient on the merits to carry the day for Purdue. The court explained that it did not regard the examiner's cryptic statement as directly applicable to the written description requirement but added that even if the examiner's statement was directed to the written description requirement, any deference due to the Patent Examiner has been overcome by Faulding's clear and convincing evidence that the specification does not support the asserted claims of the '360 Patent. Thus, the court rejected the examiner's statement on which Purdue relies not because of a misconception about the nature of the issue before it, but because the court did not find the examiner's statement persuasive in light of all the evidence in the case.

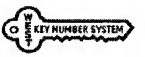
[10] Relying on the Supreme Court's decision in *Dickinson v. Zurko*, 527 U.S. 150, 119 S.Ct. 1816, 144 L.Ed.2d 143, 50 USPQ2d 1930 (1999), Purdue makes the related argument that the district court should have sustained the examiner's decision on the written description issue as long as it was supported by substantial evidence. The short answer to that argument is that this was an infringement action that originated in the district court, not an appeal from a decision of the Patent and Trademark Office Board of Appeals and Interferences, which was at issue in *Zurko*. The Administrative Procedure Act standard of review adopted in *Zurko* therefore has no application here. To be sure, as we have noted, the decision of the Patent and Trademark Office with respect to patentability is accorded deference in district court litigation, deference that takes the form of the presumption of validity that is accorded to issued patents under 35 U.S.C. § 282. *See Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555, 225 USPQ 26, 31 (Fed.Cir.1985). The court, however, was not bound by the examiner's finding in the *ex parte* application proceeding that the new claims were supported by the specification, particularly in light of the fact that the court heard extensive evidence on the issue in an adversary hearing, none of which was before the patent examiner.

III

Because we have upheld the district court's determination that the asserted claims of the '360 patent are invalid, it is unnecessary to address Faulding's cross-

appeal from the district court's finding of infringement.

AFFIRMED.



Raymond G. MAXSON, Claimant–Appellant,

v.

Hershel W. GOBER, Acting Secretary of Veterans Affairs, Respondent–Appellee.

No. 99–7160.

United States Court of Appeals, Federal Circuit.

DECIDED: Oct. 27, 2000.

Veteran appealed a Board of Veterans Appeals (BVA) decision that determined that his partial colectomy, received prior to active service, was not aggravated by his combat service and thus denied his reopened claim for service-connected benefits. The United States Court of Appeals for Veterans Claims, William P. Greene, Jr., J., 12 Vet.App. 453, affirmed BVA decision, and veteran appealed. The Court of Appeals, Pauline Newman, Circuit Judge, held that, although veteran established presumption of service-connected aggravation of his pre-service colon condition, presumption was rebutted by clear and convincing evidence.

Affirmed.

1. Armed Services ⇐104.1

A veteran is entitled to benefits for service-connected aggravation of a condition that existed before the commencement of military service if the military service caused some increase in the disability due to the preexisting condition. 38 U.S.C.A. §§ 1110, 1153.

2. Armed Services ⇐104.1

For combat veteran seeking to establish service connection for aggravation of pre-service condition to invoke presumption of service-connection by lay or other evidence in absence of official records, it must first be determined whether veteran has presented satisfactory lay or other evidence of service incurrence or aggravation of such injury or disease; next, it must be determined whether evidence is consistent with circumstances, conditions, or hardships of such service, which, if met along with first step, requires Secretary of Veterans Affairs to accept evidence as sufficient proof of service-connection regardless of absence of official records; and third, it is determined whether government came forward with enough evidence to rebut presumption with clear and convincing evidence to the contrary. 38 U.S.C.A. § 1154(b).

3. Armed Services ⇐104.2(5)

Although combat veteran established presumption of service-connected aggravation of his pre-service colon condition, veteran was not thereby entitled to benefits, since presumption was rebutted by clear and convincing evidence, including absence of any post-war medical records concerning colon-related problems for period of over 40 years. 38 U.S.C.A. § 1154(b).

4. Armed Services ⇐104.1

Evidence of a prolonged period without medical complaint can be considered, along with other factors concerning the veteran's health and medical treatment during and after military service, as evidence of whether a pre-existing condition was aggravated by military service; trier of fact should consider all of the evidence including the availability of medical records, the nature and course of the disease or disability, the amount of time that elapsed since military service, and any other relevant facts. 38 C.F.R. § 3.306(b).

5. Armed Services ⇐104.1

Whether evidentiary presumption of service-connection for aggravation of combat veteran's pre-service medical condition has been rebutted is a matter of the weight of all of the evidence, in light of the